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- a) said driving head is attached to said body at a breakaway region that provides for said driving head to break from said body when the preselected torque is applied to said driving head.
- 

The following are the amended claims noted above in a marked format indicating additions by underlining and deletions by bracketing:

1. (Amended) A closure for use in conjunction with a medical implant that is sized and shaped to operably close a channel between two spaced arms with each of said arms having an inwardly threaded surface; said closure comprising:

- a) a body having an axis of rotation and a threaded cylindrical shaped radially outward surface with threads sized and shaped to be threadably mated with [a] the threaded [surface] surfaces of [an implant] the implant arms;
- b) a break-off driving head having a first cross section associated therewith perpendicular to the axis of rotation; said driving head adapted to rotate and torque said body in said implant until a preselected torque occurs at which time said break-off head breaks from said body; and
- c) a removal head external of said body and located

between said driving head and said body; said removal head having a second cross section associated therewith perpendicular to the axis of rotation with said [secured] second cross section being different from said first cross section.

2. (Amended) The closure according to Claim 1 wherein:

- a) said driving head is joined to said body by a breakaway region such that said driving head breaks away from said body when [a predetermined] the preselected torque is applied to the driving head.

3. (Amended) The closure according to Claim 1 wherein:

- a) said removal head is axially centered [and positional between said body and said driving head].

5. (Amended) A medical implant system comprising:

- a) an open headed medical implant having a head formed by a pair of spaced interiorly threaded arms defining a channel therebetween sized and shaped to receive a rod member; and;
- b) a closure member including:
  - i) [. ] a body having an axis of rotation and a threaded cylindrical shaped radially outward surface with threads sized and

shaped to be threadably mated with said threaded arms;

- ii) [.] a driving head having a first cross section associated therewith perpendicular to the axis of rotation; said driving head operably allowing a user to rotate and torque said body until a preselected torque occurs whereat said driving head breaks from said body; and
- iii) [.] a removal head located external of said body and between said body and said driving head; said removal head having a second cross section associated therewith perpendicular to the axis of rotation with said second cross section being different in comparison to said first cross section.

6. (Amended) The implant system according to Claim 5 wherein:

- a) said driving head is joined to said body by a breakaway region such that said driving head breaks away from said body when [a predetermined] the preselected torque is applied to the driving head.

7. (Amended) The implant system according to Claim 5 wherein:

- a) said removal head is axially centered [and positional between said body and said driving head].

9. (Amended). A closure for use in conjunction with an open headed medical implant having a pair of interiorly threaded arms forming a channel therebetween for receiving the closure; said closure closing said channel upon being received between said arms; said closure comprising:

- a) a cylindrical shaped body with a radial outward threaded surface sized and shaped to be threadably received between the arms of [such an open ended] the implant; said body having an axis of rotation;
- b) a driving head axially aligned with and attached to said body and having a first gripable outer surface; said driving head operably rotating and torquing said body and breaking from said body at a preselected torque; and
- c) a removal head axially aligned with and attached to said body for removing said body from the implant; said removal head being located external

of said body and between said body and said driving head; said removal head [and] having a second gripable outer surface; said first and second gripable outer surface being different in configuration so as to prevent a tool used with said first surface from also accidentally gripping said second surface.

10. (Amended) The closure according to Claim 9 wherein:
- a) said driving head is attached to said body at a breakaway region that provides for said driving head to break from said body when [a] the preselected torque is applied to said driving head.

Remarks:

The Office Action mailed March 6, 2002 has been received and carefully considered. Reconsideration of the application as amended hereby is respectfully requested.

Claim 1 was rejected as anticipated by Mellinger. Mellinger is a 102(e) reference and it is quite likely, especially in view of the interpretation given to it, that applicant could swear back that reference. However, it is believed that swear back will not be necessary in view of the following. Nevertheless, applicant reserves the right to swear back, if it is later deemed

necessary.

In particular, Claim 1 is directed to a closure for closing a gap or channel between spaced elements of a medical implant wherein the closure itself has a breakoff head for installation. Claim 1 has been amended to emphasize this feature. While Mellinger shows a closure or closure member 16 that closes a channel 20 between two spaced arms of a bone screw, the closure of Mellinger includes neither a break-off head nor a removal head. The Mellinger device is used with a set screw 70 that is mounted in a bore in the closure. It is noted that the set screw includes a break-off head 74 and flanges 80 for removal, but the closure does not. In particular, the Mellinger closure slides in from the side rather than being screwed into the opening. Consequently, it is urged that Mellinger fails to teach or show a closure of the type of device claimed wherein there is a closure with a driving head and a removal head.

There are substantial additional differences between applicant's device and Mellinger's device, including that the closure of Mellinger needs neither a driving head nor a removal head because it is never screwed into the channel, rather it slides in parallel to a rod held in the channel and is removed the same way. Consequently, it teaches against combining the closure of the illustrated device somehow with the teachings of the set screw that is used with the Mellinger closure, since

there would be no way to screw the Mellinger head in without substantial further teachings and the device itself teaches away from a screw in closure.

Independent Claim 9, as well as the claims dependent from 1 and 9, are believed to distinguish from Mellinger for the same reasons as noted above for Claim 1.

Independent Claim 1 was rejected as anticipated under 102(e) as being anticipated by Gourney. Claim 1 has been amended to call for a removal head that is located externally. Although Gourney is directed to a screw in closure of the type called for and although it has an external break-off driving head, it does not have an external removal head that remains after the driving head breaks away, but rather uses an internal faceted bore for removal. In order to produce applicant's invention, one must figure out to place the removal head between the break-off head and the body which is not in any way taught or suggested by Gourney. Therefore, Claim 1 and the claims dependent from Claim 1 are urged to distinguish over Gourney.

Claim 5 was rejected under 103 upon a combination of Cotrel and Gourney. While Cotrel and Gourney are both closures and although Gourney includes a break-off driving head, neither include an external removal head that is positioned between the breakoff head and the body of the closure so it becomes available for use in removing the closure after the break-off driving head

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breaks away. Consequently, it is urged that Claim 5 and the claims dependent from Claim 5 distinguish over any teachings derived from the combination of Gourney and Cotrel.

It is noted that applicant developed a set screw of the type used in the Mellinger patent approximately six years ago and that such set screw was offered for sale by Sofamor at that time. This set screw had a body with both a removal head and driving head, but is distinguishable from the claimed subject matter in two ways. The claimed subject matter is directed to a closure between two spaced arms and the earlier device was a set screw for placement in an encircling threaded bore. Further, and perhaps more importantly, the set screw driving and removal heads were coaligned and had exactly the same cross section, so installation tools could accidentally grip the removal head on insertion, whereas the claimed device has driving and removal heads with different cross sections or different gripable surfaces to prevent this possibility. The earlier set screw designed by applicant in combination with others and described above is shown in Figs. 12 to 15 of U.S. Patent 6,224,596, but not claimed therein. As noted above, such a set screw was not a closure and could be used with the previously cited prior art to replace the central set screw, shown at number 74 in the Mellinger patent but not the Mellinger closure which has a slide in type design.

Therefore, it is urged that pending Claims 1 to 13 are allowable and notice to that effect is earnestly solicited.

The Examiner is invited to contact the undersigned by telephone, if prosecution of this application can be expedited thereby.

Respectfully Submitted,



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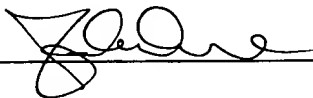
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231 on May 7, 2002.

Roger P. Jackson  
(Applicant)

By



May 7, 2002

(Date of Signature)